

lication No.:

10/534,725 May 12, 2005

st Inventor:

H. Abe

For:

Indole Derivatives as Somatostatin Agonists or Antagonists

Attv. Dkt. No.

3122 USOP

## Information Disclosure Statement

Commissioner for Patents P.O. Box 1450 Alexandria, VA 23313-1450

Sir:

Pursuant to 37 CFR §1.56, 1.97 and 1.98, Applicants' request consideration of the reference listed on the attached form PTO-1449 under §1.97(b). Copies of foreign patent documents and non-patent literature are enclosed.

This statement is being timely filed before the mailing of a first Office Action on the merits. No fee is required for this filing.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully invited to call Applicants' attorney.

Respectfully submitted.

Dated: July \_, 2005

(847) 383-3391 (847) 383-3372 Elaine M. Ramesh, Ph.D., Reg. No. 43,032 Mark Chao, Ph.D., Reg. No. 37,293

Attorney for Applicants Customer No. 23115

Takeda Pharmaceuticals North America, Inc. Intellectual Property Department 475 Half Day Road Lincolnshire, IL 60069 USA

U.S. Patent Application Serial No.: 10/534,725

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1449/PTO

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Sheet 1

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)

of 3

/Noble Jarrell/

Application Number	10/534,725
Filing Date	May 12, 2005
First Named Inventor	H. Abe
Art Unit	tba
Examiner Name	tba
Attomey Docket Number	3122 US0P

Considered

11/09/2007

U. S. PATENT DOCUMENTS Pages, Columns, Lines, Where Document Number Name of Patentee or Initials\* MW-DU-AAAA Applicant of Cited Document Relevant Passages or Relevant Figures Appear Number-Kind Code<sup>2</sup> (V Ancoun US- 2002/00901090 07-11-2002 B. Cole et al. US- 6,329,389 12-11-2001 Takeda Chemical Industries US- 2004/0058877 03-25-2004 US- 6,696,418 02-24-2004 Pfizer Inc. US-6,025,372 02-15-2000 Merck & Co., Inc. US- 6,057,338 05-02-2000 Merck & Co., Inc. US-5,773,441 06-30-1998 Eli Lilly and Company US- 2004/0024067 02-05-2004 S. Remiszewski et al. US- 6,387,932 05-14-2002 Merck & Co., Inc. US- 2003/0229200 12-11-2003 L. Chen et al. US- 2003/0195212 T. Lundstedt et al. 10-16-2003 US- 2002/0016298 02-07-2002 B. Hav et al. US- 2002/0128206 09-12-2002 B. Hay et al. US- 6.599.795 07-29-2003 Mitsubishi Denki Kabushiki Kaisha US-6,600,015 07-29-2003 Hoffmann-La Roche Inc. US-6,552,065 04-22-2003 Novartis AG US-

Examiner Initials*	Cita No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	Ι.
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		EP 1 086 947	03-28-2001	Pfizer Products Inc.		
		WO 03/042204	05-22-2003	Takeda Chemical Industries		V
		EP 1 437 351	07-14-2004	Takeda Chemical Industries		
		WO 99/52875	10-21-1999	Takeda Chemical Industries		
		WO 01/25228	04-12-2001	Takeda Chemical Industries		1
		EP 1 227 090	07-31-2002	Takeda Chemical Industries		

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Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Palent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.J./

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)

Sheet 2 of 3

Application Number	10/534,725	
Filing Date	May 12, 2005	
First Named Inventor	H. Abe	
Art Unit	tba	
Examiner Name	tba	
Attomory Docket Number	2122 LICOD	_

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Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear
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		WO 01/55106	08-02-2001	Melacure Therapeutics AB		
		GB 2 140 423	11-28-1984	Kimberly-Clark Corporation		
		WO 00/26188	03-11-2000	Max-Planck-Gesellschaft		1
		EP 0 761 220	03-12-1997	Eli Lilly and Company		
		WO 98/44921	10-15-1998	Merck & Co., Inc.		
		WO 98/45285	10-15-1998	Merck & Co., Inc.		
Examiner	_	/Noble Jarrell/		Date	11/00/2007	

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of 3

Sheet 3

Application Number	10/534,725
Filing Date	May 12, 2005
First Named Inventor	H. Abe
Art Unit	tba
Examiner Name	tba
Attorney Docket Number	3122 US0P

U. S. PATENT DOCUMENTS Pages, Columns, Lines, Where Document Number Publication Date Relevant Passages or Relevant Initials\* No MM-DD-YYYY Applicant of Cited Document Number-Kind Code<sup>2</sup> (V Anoung Figures Appear US-US-US-US. US. US-116 US-211 US-US-US-US-

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		WO 02/16350	02-28-2002	Takeda Chemical Industries		V
		WO 01/74844	10-11-2001	F. Hoffmann-La Roche AG		
		WO 02/22577	03-21-2002	Novartis-Erfindungen		L
		GB 2 351 733	01-10-2001	Merck & Co., Inc.		Ш
		JP 52-148032	12-08-1977	Sankyo Co., Ltd.		V
		WO 03/082819	10-09-2003	Nippon Chemiphar Co., Ltd.		V
Examiner Signature	Т	/Noble Jarrell/		Date Considered	11/09/2007	_

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INFORMATION DISCLOSURE	Filing Date	May 12, 2005
STATEMENT BY APPLICANT	First Named Inventor	H. Abe
(Use as many sheets as necessary)	Art Unit	tba
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Sheet 1 of 1	Attorney Docket Number	3122 US0P

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, old pandor country where published.	T²
		D. MALEY, et al., "Expedient Solid-Phase Synthesis of Fluorogenic Protease Substrates Using the 7-Amino-4-Carbamoylmethylcoumarin (ACC) Fluorophore", <u>J. Org. Chem.</u> (2002) Vol. 67, No. 3, pages 910 - 915	
		F. HERNANDEZ, et al., " A Short Synthesis of de-'prenyl'-ardeemin", Tetrahedron Letters 44, (2003), pages 3367 - 3369	
		<ol> <li>OJIMA, et al., "Design, Synthesis and Sar of RGD Peptide Hybrids as highly Efficient Inhibitors of Platelet Aggregation", Bioorganic &amp; Medicinal Chemistry Letters, (1995), Vol. 5, No. 17, pages 1941 - 1946</li> </ol>	
		L. GRAF, et al., "Electrostatic Complementarity within the Substrate-Binding Pocket of Trypsin", Proc. Natl. Acad. Sci. USA, (1988), Vol. 85, pages 4961 - 4965	
		T. TANAKA, et al., "Human Leukocyte Cathepsin G. Subsite Mapping with 4-Nitroanlides, Chemical Modification, and Effect of Possible Cofactors", <u>Biochemistry</u> , (1985), Vol. 24, pages 2040 - 2047	
		J. MACOR, et al., "The Discovery of a Novel and Potent Benzodiazepine Receptor Pharmacophore", Bioorganic & Medicinal Chemistry Letters, Vol. 5, No. 20, pages 2397 - 2402	
		A. VARNAVAS, et al., "Anthranoyl-Anthranilic Acid: A Template for the Development of a New Class of Cholecystokinin Receptor Ligands", Pharmazie, (1996), Vol. 51, No. 10, pages 697 - 700	
		A. BERNHARDT, et al., "The Solid-Phase Synthesis of Side-Chain-Phosphorylated Peptide-4-Nitroanilides", J. Peptide Res. (1997), Vol. 50, Vol. 2, pages 143 - 152	
		M. MERGLER, et al., "Protected Peptide p-nitroanilides by Solid-Phase Synthesis", Letters in Peptide Science, (2000), Vol. 7, No. 1, pages 1 - 7	
		A. ESCHERICH, et al., "Peptide/Benzodiazepine Hybrids as Ligands of CCKa and CCKb Receptors", Biopolymers, (2001), Vol. 56, No. 2, pages 55 - 76	

	and Corts Receptors , <u>Biophylliers</u> , (2001), Vol. 36, No. 2, pages 65				
Examiner	/Noble Jarrell/	Date	11/09/2007	- 1	
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